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Docket No.: C035795/0125237

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
Jerome O. CANTOR, *et al*,

Serial No.: 09/863,849

Filed: May 23, 2001

For: **METHOD FOR TREATING
RESPIRATORY DISORDERS**

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) Examiner: Michael C. Henry
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) Art Unit: 1623
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New York, New York
April 24, 2006

RESPONSE TO OFFICE ACTION

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed on November 23, 2005, which set a shortened statutory period of three months for response. A two-month extension of time is hereby requested. Accordingly, this response is filed timely upon mailing with an executed certificate of mailing on or before April 24, 2006, since April 23, 2006, fell on a Sunday. 37 CFR § 1.7, 1.8, 1.136; and 35 USC § 21 (b). Enclosed is a check in the amount of \$450.00 to cover the fee for the extension of time. 37 CFR § 1.17.

It is not believed that this response occasions any additional fees, but if any additional fees are required, please charge the same (or credit any overpayment) to Deposit Account No. 02-4467.

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This application has been pending for five years now. The Examiner stated in the last office action that he believed certain subject matter was allowable over the art. When the applicants accepted that administrative finding, the Examiner pulled his decision, and made a new ground of rejection. Obviously, the applicants are disappointed in the Examiner's decision to go against his prior finding. And the term of a patent that may issue is being minimized by that action.

In any event, as explained below, the new rejection is no better than the last. There are several gaps that exist between the references, on the one hand, and the pending claims, on the other. As shown below, the references do not fill the gaps, and neither does that Examiner's reasoning.

Thus, for the reasons presented below, it respectfully is submitted that the rejection should be withdrawn and that the application is in condition for allowance.

In making the rejection, the Examiner relied on Cantor as follows:

Cantor discloses a system for delivering a polysaccharide formulation to a respiratory tract of a mammal, comprising: a mixture comprising a polysaccharide (hyaluronic acid), that can be delivered via a route aerosol inhalation by a nebulizer (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising a polysaccharide. Furthermore, it should be noted that the nebulizer contains the said canister, valve and nozzle, claimed by applicant.

The Examiner further relied on Green as follows:

Green discloses an aerosol formulation for administration by inhalation containing a medicament, a sugar (a carbohydrate) and a fluorocarbon propellant for treating respiratory disorders (see abstract). Green discloses that the medicament can include drugs such as terbutaline,

penicillins, ephedrine (see page 2, line 22-page 3, line 9). It should be noted that Green, like Cantor, also uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders).

The Examiner acknowledged that the pending claims require a mixture that includes a polysaccharide having a high molecular weight of between about 50,000 and 1.5×10^6 Daltons at a concentration of less than about 5.0 mg/ml (w/v) of polysaccharide, and conceded that neither Cantor nor Green disclose the molecular weight and concentration parameters required by the claims.

To fill the acknowledged gaps, the Examiner contended that one would have been motivated "to prepare the composition of Cantor comprising different concentrations, molecular weights, or particle sizes of polysaccharide...depending on need."^{1/}

Thus, although the Examiner acknowledged these differences, the Examiner summarily dismissed them as need - based parameters. As discussed below, the Examiner's argument fails because it is unsupported by the references, or logic, or law.

Initially, none of the references relied upon by the Examiner disclose **any** molecular weights or concentrations of any polysaccharide in **any** composition whatsoever, much less as required by the claims. In fact, none of the references of the

^{1/} It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the composition of Cantor comprising different concentrations, molecular weights or particle size of the polysaccharide in combination with a drug disclosed by Green such as terbutaline, penicillins, ephedrine and a fluorocarbon propellant to be used as an inhalant aerosol formulation for treating respiratory conditions or disorders, depending on need (like the severity of the respiratory disorder).

rejection disclose **any** molecular weight or concentration of a polysaccharide at all. And the Examiner has not addressed that fact. In the absence of any factual support, the Examiner's "need" argument is entirely misplaced.

Before there can be any "need," there must first be a recognition in the art that the molecular weight and concentration which is argued by the Examiner to be a "need" was known to be such in the references. Here, none of the references establish that the parameters recited were known to be "needed." In fact, the only knowledge about molecular weight and concentration of polysaccharides in any of the references, was that they were **unknown**. "Depending on need," just like obviousness, cannot be based on the **unknown**. *In re Spormann*, 150 USPQ 449, 452 (CCPA 1966); *Deuel, supra*. at 1215. That, however, is precisely what the Examiner argues in the final action. And, there is **no** "overlap" of ranges here, and the Examiner has not even contended as much.

Thus, the Examiner's "depending on need" argument is unsupported by the references of the rejection. For this reason, the rejection is erroneous as a matter of fact and law and should be reversed.

Moreover, the parameters claimed are not only **not** disclosed in the references, but further would **not** have been "the result of obvious experimentation, since ... any such experimentation would not have come from *within the teachings of the art*." *In re Waymouth*, 182 USPQ 290, 292 (CCPA 1974) (Emphasis original). Nothing in the references or in the Examiner's reasoning would have led one to the parameters in

compositions as claimed in all claims. Nothing in the references of the rejection would have led one to experiment or alter any of the claimed parameters in any way.

Bottom line, none of the references disclose or provide any suggestion to have made compositions having the polysaccharides as claimed. And the polysaccharide molecular weights and concentrations claimed certainly were not a choice presented by the references. For this further reason, the rejection is erroneous as a matter of fact and law and should be withdrawn.

Thus, for each of the foregoing reasons, since all claims contain these or similar range limitations, the rejection of all claims should be reversed. *Cf., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Further, with regard to the Examiner's apparent argument that "depending on need" renders any and all parameters of any and all compositions obvious *per se*, as also is well settled, there are no *per se* rules of obviousness. *In re Ochiai*, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) ("reliance on *per se* rules of obviousness is legally incorrect and must cease."); and see MPEP § 2116.01 at 2100-45 (Seventh Edition, Rev. 1, Feb. 2000). But a *per se* rule of obviousness, that if a parameter recited in a claim is "needed" - though no reference supports that it is - then the claim is obvious, is precisely the *per se* rule that the Examiner has employed here in attempting to rehabilitate the rejection. Bottom line, "depending on need" is simply not the stuff of a § 103 rejection.

Thus, because the references do not support the Examiner's "depending on need" argument, the rejection should be withdrawn.

In addition, as also is fundamental, in making a rejection for obviousness, an Examiner is required to provide clear evidence for why one would have been motivated to pick and combine the references relied upon by the Examiner and why, once the references have been selected for combination, one would then have been led to select and combine the particular elements the Examiner picked from their disclosures to arrive at a combination as claimed. See *In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (“**Because we do not discern any** finding by the Board that there was a suggestion, teaching, or **motivation to combine the prior art references cited** against the pending claims, the Board’s **conclusion of obviousness, as a matter of law, cannot stand.**”). In this case, the Examiner did not allege any reason for why one would have been motivated to select and combine Cantor and Green. For this reason alone, the rejection should be withdrawn.

Even if the Examiner had identified **motivation** for one would have been led to select and combine Cantor and Green, the rejection still would be deficient because the Examiner did not even allege that one would have then been **motivated** to use Breen’s propellant with Cantor’s composition. Instead, the sole argument asserted in support of the proposed modification of Cantor, was that one would have combined Green’s components with Cantor’s “depending on need.”

Not only are the Examiner’s “depending on need” arguments not supported by any evidence or reference, but contrary to those assertions, one of ordinary skill does not substitute elements without a factually based suggestion to do so. One of ordinary skill does not make substitutions or combinations for the sake of it, or merely because

something might be just as good as it was without the proposed substitution. One of ordinary skill follows teachings or suggestions that one ***should*** deviate from the disclosure of a reference, teachings or suggestions which would have “***strongly motivated***” one to pick the particular elements required by the claims and make a composition as claimed [See *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1983)], the type of motivation that would have “***impelled***” one to do so [See *Ex parte Levengood*, 28 USPQ2d 1300, 1302 (B.P.A.I. 1993)], or the type of suggestion that the selection and combination “***should***” be made [See *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964)]. That is what a conclusion of obviousness requires. See, again, *Levengood*, 28 USPQ2d at 1302.

“Depending on need” falls far short of the requisite suggestion and motivation which would have led one to deviate from the Cantor composition and rebuild the Cantor composition so that they would have arrived at what is claimed. Bottom line, nothing in either reference shows any “need” to alter the Cantor composition in any way. Should the rejection be maintained it respectfully is requested that the Examiner provide authority that would support the argument that “depending on need,” when the references do not support any such need, is sufficient to establish obviousness.


Thus, for the reasons presented below, it respectfully is submitted that the rejection should be withdrawn and that the application is in condition for allowance.

In view of the foregoing, favorable action on the merits, including withdrawal of each rejection and allowance of all claims, respectfully is submitted.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Mail Stop Amendment, Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 24, 2006.


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Respectfully submitted,

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